Draft Guidance for Industry Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products Chemistry, Manufacturing, and Controls Documentation

Docket No. 99D-1454, CDER 98185, June 2, 1999 Page 29657 [FR Doc. 99-13921]

Line 411 - Spray Weight Delivery

In general, pump spray weight delivery acceptance criteria should control the weight of the individual sprays to within ± 15 percent of the target weight and 412 their mean weight to within ± 10 percent of the target weight. 413

For small dosage pumps (e.g. $20 \,\mu l$, $25 \,\mu l$...), the pump spray weight delivery acceptance criteria may need to be set based on the capabilities of the nasal spray pump as the relative variation of the pump mechanism is greater due to the small dosages being delivered.

99D-1454

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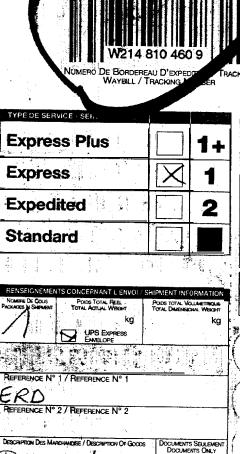
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